

detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. An AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(b) *Classification*. Class III (premarket approval)

(c) *Date PMA or notice of PDP is required*. No effective date has been established of the requirement for premarket approval. See § 870.3.

[68 FR 61344, Oct. 28, 2003; 69 FR 10615, Mar. 8, 2004]

#### § 870.5325 Defibrillator tester.

(a) *Identification*. A defibrillator tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

(b) *Classification*. Class II (performance standards).

#### § 870.5550 External transcutaneous cardiac pacemaker (noninvasive).

(a) *Identification*. An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The pulse from the device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

(b) *Classification*. Class II. The special controls for this device are:

- (1) "American National Standards Institute/American Association for Medical Instrumentation's DF-21 'Cardiac Defibrillator Devices' " 2d ed., 1996, and
- (2) "The maximum pulse amplitude should not exceed 200 milliamperes. The maximum pulse duration should not exceed 50 milliseconds."

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

#### § 870.5800 Compressible limb sleeve.

(a) *Identification*. A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.

(b) *Classification*. Class II (performance standards).

#### § 870.5900 Thermal regulating system.

(a) *Identification*. A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate patient temperature.

(b) *Classification*. Class II (performance standards).

#### § 870.5925 Automatic rotating tourniquet.

(a) *Identification*. An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.

(b) *Classification*. Class II (performance standards).

## PART 872—DENTAL DEVICES

### Subpart A—General Provisions

#### Sec.

##### 872.1 Scope.

##### 872.3 Effective dates of requirement for premarket approval.

##### 872.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

### Subpart B—Diagnostic Devices

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##### 872.1740 Caries detection device.

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 872.3140 Resin applicator.  
 872.3150 Articulator.  
 872.3165 Precision attachment.  
 872.3200 Resin tooth bonding agent.  
 872.3220 Facebow.  
 872.3240 Dental bur.  
 872.3250 Calcium hydroxide cavity liner.  
 872.3260 Cavity varnish.  
 872.3275 Dental cement.  
 872.3285 Preformed clasp.  
 872.3300 Hydrophilic resin coating for dentures.  
 872.3310 Coating material for resin fillings.  
 872.3330 Preformed crown.  
 872.3350 Gold or stainless steel cusp.  
 872.3360 Preformed cusp.  
 872.3400 Karaya and sodium borate with or without acacia denture adhesive.  
 872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.  
 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.  
 872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive.  
 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.  
 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.  
 872.3500 Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.  
 872.3520 OTC denture cleanser.  
 872.3530 Mechanical denture cleaner.  
 872.3540 OTC denture cushion or pad.  
 872.3560 OTC denture reliner.  
 872.3570 OTC denture repair kit.  
 872.3580 Preformed gold denture tooth.  
 872.3590 Preformed plastic denture tooth.  
 872.3600 Partially fabricated denture kit.  
 872.3630 Endosseous dental implant abutment.  
 872.3640 Endosseous dental implant.  
 872.3645 Subperiosteal implant material.  
 872.3660 Impression material.  
 872.3661 Optical Impression Systems for CAD/CAM.  
 872.3670 Resin impression tray material.  
 872.3680 Polytetrafluoroethylene (PTFE) vitreous carbon materials.  
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872.3700 Dental mercury.  
 872.3710 Base metal alloy.  
 872.3730 Pantograph.  
 872.3740 Retentive and splinting pin.  
 872.3750 Bracket adhesive resin and tooth conditioner.  
 872.3760 Denture relining, repairing, or rebasing resin.  
 872.3765 Pit and fissure sealant and conditioner.  
 872.3770 Temporary crown and bridge resin.  
 872.3810 Root canal post.  
 872.3820 Root canal filling resin.  
 872.3830 Endodontic paper point.  
 872.3840 Endodontic silver point.  
 872.3850 Gutta percha.  
 872.3890 Endodontic stabilizing splint.  
 872.3900 Posterior artificial tooth with a metal insert.  
 872.3910 Backing and facing for an artificial tooth.  
 872.3920 Porcelain tooth.  
 872.3930 Tricalcium phosphate granules for dental bone repair.  
 872.3940 Total temporomandibular joint prosthesis.  
 872.3950 Glenoid fossa prosthesis.  
 872.3960 Mandibular condyle prosthesis.  
 872.3970 Interarticular disc prosthesis (interpositional implant).  
 872.3980 Endosseous dental implant accessories.

**Subpart E—Surgical Devices**

872.4120 Bone cutting instrument and accessories.  
 872.4130 Intraoral dental drill.  
 872.4200 Dental handpiece and accessories.  
 872.4465 Gas-powered jet injector.  
 872.4475 Spring-powered jet injector.  
 872.4535 Dental diamond instrument.  
 872.4565 Dental hand instrument.  
 872.4600 Intraoral ligature and wire lock.  
 872.4620 Fiber optic dental light.  
 872.4630 Dental operating light.  
 872.4730 Dental injecting needle.  
 872.4760 Bone plate.  
 872.4840 Rotary scaler.  
 872.4850 Ultrasonic scaler.  
 872.4880 Intraosseous fixation screw or wire.  
 872.4920 Dental electrosurgical unit and accessories.

**Subpart F—Therapeutic Devices**

872.5410 Orthodontic appliance and accessories.  
 872.5470 Orthodontic plastic bracket.  
 872.5500 Extraoral orthodontic headgear.  
 872.5525 Preformed tooth positioner.  
 872.5550 Teething ring.  
 872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

**Subpart G—Miscellaneous Devices**

- 872.6010 Abrasive device and accessories.
- 872.6030 Oral cavity abrasive polishing agent.
- 872.6050 Saliva absorber.
- 872.6070 Ultraviolet activator for polymerization.
- 872.6080 Airbrush.
- 872.6100 Anesthetic warmer.
- 872.6140 Articulation paper.
- 872.6200 Base plate shellac.
- 872.6250 Dental chair and accessories.
- 872.6290 Prophylaxis cup.
- 872.6300 Rubber dam and accessories.
- 872.6350 Ultraviolet detector.
- 872.6390 Dental floss.
- 872.6475 Heat source for bleaching teeth.
- 872.6510 Oral irrigation unit.
- 872.6570 Impression tube.
- 872.6640 Dental operative unit and accessories.
- 872.6650 Massaging pick or tip for oral hygiene.
- 872.6660 Porcelain powder for clinical use.
- 872.6670 Silicate protector.
- 872.6710 Boiling water sterilizer.
- 872.6730 Endodontic dry heat sterilizer.
- 872.6770 Cartridge syringe.
- 872.6855 Manual toothbrush.
- 872.6865 Powered toothbrush.
- 872.6870 Disposable fluoride tray.
- 872.6880 Preformed impression tray.
- 872.6890 Intraoral dental wax.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 30097, Aug. 12, 1987, unless otherwise noted.

**Subpart A—General Provisions****§ 872.1 Scope.**

(a) This part sets forth the classification of dental devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a dental device that has two or more types of uses (e.g., used both as a diag-

nostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh.guidance.html>.

[52 FR 30097, Aug. 12, 1987, as amended at 68 FR 19737, Apr. 22, 2003]

**§ 872.3 Effective dates of requirement for premarket approval.**

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b)